1646

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Michel REVEL et al

Application No.: 09/462,416

Filed: April 13, 2000

For: CHIMERIC INTERLEUKIN-6 SOLUBLE RECEPTOR/LIGAND ...

Art Unit: 1646

Examiner: N. Basi

Washington, D.C.

Atty.'s Docket: REVEL=15

Date: October 29, 2001

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is a [ ] Amendment [X] Response to Restriction Requirement _____
in the above-identified application.

[ ] Small Entity Status: Applicant(s) claim small entity status. See 37 C.F.R. §1.27.

[XX] No additional fee is required.

[ ] The fee has been calculated as shown below:

	(Col. 1) CLAIMS REMAINING AFTER AMENDMENT		(Col. 2) HIGHEST NO. PREVIOUSLY PAID FOR	(Col. 3) PRESENT EXTRA EQUALS	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
TOTAL	*	MINUS	** 20	0	x 9	$		x 18	$
INDEP.	*	MINUS	*** 3	0	x 42	$		x 84	$
FIRST PRESENTATION OF MULTIPLE DEP. CLAIM					+ 140	$		+ 280	$
					ADDITIONAL FEE TOTAL	$	OR	TOTAL	$

* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 20, write "20" in this space.

*** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment of the number of claims originally filed.

[XX] Conditional Petition for Extension of Time

If any extension of time for a response is required, applicant requests that this be considered a petition therefor.

[ ] It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

Small Entity			Other Than Small Entity		
Response Filed Within			Response Filed Within		
[ ]	First	- $ 55.00	[ ]	First	- $ 110.00
[ ]	Second	- $ 200.00	[ ]	Second	- $ 400.00
[ ]	Third	- $ 460.00	[ ]	Third	- $ 920.00
[ ]	Fourth	- $ 720.00	[ ]	Fourth	- $ 1440.00
Month After Time Period Set			Month After Time Period Set		

[ ] Less fees ($_____) already paid for ___ month(s) extension of time on _____.

[ ] Please charge my Deposit Account No. 02-4035 in the amount of $_____.

[ ] Credit Card Payment Form, PTO-2038, is attached, authorizing payment in the amount of $_____.

[ ] A check in the amount of $_____ is attached (check no.).

[XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR §1.16 and all patent processing fees under 37 CFR §1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR §1.18.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#11

Atty. Docket: REVEL=15

In re Application of:	)	Art Unit: 1646
Michel REVEL et al	)	Examiner: N. Basi
Appln. No.: 09/462,416	)	Washington, D.C.
IA Filing Date: July 19, 1998	)	October 29, 2001
For: CHIMERIC INTERLEUKIN-6 SOLUBLE RECEPTOR/LIGAND PROTEIN, ANALOGS THEREOF AND USES THEREOF	)	

RESPONSE

Honorable Commissioner for Patents
Washington, D.C. 20231

Sir:

The present communication is responsive to the official action of October 3, 2001. Claims 1-37 presently appear in this case. No claims have yet been examined on the merits. All of the claims have been subject to a restriction requirement. Reconsideration and withdrawal of the restriction requirement and action on all of the claims now present in the case are hereby respectfully urged.

The examiner states that applicants are required, in accordance with 37 C.F.R. §1.499 to elect a single invention from among the following groups:

Group I, including claims 1-15 and 32-36, drawn to chimeric construct of glycosylated soluble IL-6 receptor and IL-6 protein and biologically active fragments;

Group II, including claims 16-26, drawn to DNA encoding construct of glycosylated soluble IL-6 receptor and interleukin 6 protein and biologically active fragments, vector containing said construct, cell containing said construct and methods of producing said construct;

Group III, including claims 28 and 29 (and also presumably claim 27), drawn to use of the chimeric construct of claim 1 for eliciting engraftation of human hematopoietic cells in bone marrow transplantation ("use" claim being interpreted as method of treatment);

Group IV, including claim 30, drawn to use of the chimeric construct of claim 1 as an active ingredient for protecting liver against hepatotoxic agent ("use" claim being interpreted as method of treatment);

Group V, including claim 31, drawn to use of the chimeric construct of claim 1 as an active ingredient for increasing hematopoiesis ("use" claim being interpreted as method of treatment); and

Group VI, including claim 37, drawn to use of the chimeric construct of claim 33 for treating cancers, enhancing

bone marrow transplantations, treating liver or neurological disorders, and increasing hematopoiesis.

The examiner states that the inventions listed as Groups I-VI do not relate to a single general inventive concept because they lack the same or corresponding special technical features. The examiner states that the only technical feature common to the present claims is that they are concerned with sIL-6R/IL-6 fusion proteins, but that this protein was known in the prior art and, thus, a technical relationship does not exist between the claimed groups. This restriction requirement is respectfully traversed.

In order to be responsive, applicants hereby elect, with traverse, Group I, including claims 1-15 and 32-36. It is urged, however, that none of the references noted by the examiner disclose the present invention as recited in claim 1, i.e., a chimera "comprising a fusion protein product between essentially all of the naturally-occurring form of sIL-6R and essentially all of the naturally-occurring form of IL-6, said sIL-6R/IL-6 and analogs thereof being glycosylated in a similar fashion to the glycosylation of naturally-occurring sIL-6R and IL-6". The examiner cites references AA, AB, AC, AD, AE, AF, AG, AH and AI. However, references AC, AE and AI are not available as references as their effective filing date is subsequent to the July 10, 1997, effective filing date of

the present application, which is the filing date of applicants' Israeli priority application. This application was filed in the English language and is of record in this case so that the examiner can ascertain that these references are not available.

With respect to the remaining documents, only Fischer (AH) discloses a fusion protein product. The remaining references only disclose complexes formed when IL-6 and sIL-6R are brought together. These certainly do not anticipate the fusion protein of present claim 1. The fusion protein of reference AH does not anticipate the present claim 1 as the protein of Fischer is shorter in that it excludes the N-terminal Ig domain, as well as the C-terminal tether domain of IL-6R (see page 143 of Fischer). Furthermore, the protein of Fischer cannot be glycosylated in a similar fashion to the glycosylation of naturally-occurring sIL-6R and IL-6, as it is expressed in yeast. The examiner's attention is invited to the discussion of this reference in the background section of the present specification in the paragraph bridging pages 2 and 3.

The protein of Fischer is distinguished from those of the present invention. The definition of "essentially all" as appearing in the specification does not comprehend the truncated IL-6R of Fischer, nor does the definition of

"analogs" comprehend such truncated IL-6R. Further, the term "glycosylated in a similar fashion to the glycosylation of naturally-occurring sIL-6R and IL-6" does not read on the glycosylation which occurs when the proteins are expressed in yeast. Accordingly, the examiner is incorrect in stating that the technical feature common to the present claims was known from the prior art. As all of the present claims have in common the technical feature of the protein of claim 1, all should be examined together in this case. Reconsideration and withdrawal of this restriction requirement are, therefore, respectfully urged.

The examiner states that the present claims are directed to more than one species of the generic invention. The examiner states that claim 31 is drawn to species including increasing hematopoiesis, treating liver condition and treating neurological condition and that claim 37 is drawn to the species of treating cancers, enhancing bone marrow transplantations, treating liver or treating neurological disorders or increasing hematopoiesis. The examiner has required applicants to elect a single species to which the claims will be restricted if no generic claim is finally held to be allowable.

Applicants hereby elect the species of hematopoiesis. It is understood, however, that if the elected

species is found to be allowable, then all of the species will be examined in this case.

Accordingly, reconsideration and withdrawal of this restriction requirement and examination of all the claims now present in the case are earnestly solicited.

Respectfully submitted,

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